

Prior Authorization DRUG Guidelines

Afinitor (everolimus)

Effective Date: 10/22/13

Date Developed: 9/3/13 by Albert Reeves MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Afinitor inhibits IL-2 and other cytokine receptor-dependent signal transduction mechanisms via action on [mTOR](#) and thereby blocks activation of [T](#) and [B cells](#). mTOR is a [protein](#) encoded by the *MTOR* [gene](#) which regulates numerous cell growth properties. Thus, it is used in clinical practice as an immunosuppressant/antiproliferative medication.

Pre-Authorization Criteria: advanced hormone receptor-positive, HER2-negative **breast** cancer in postmenopausal women (in combination with exemestane and after letrozole or anastrozole failure); advanced, metastatic or unresectable **pancreatic** neuroendocrine tumors (PNET); **renal angiomyolipoma** with tuberous sclerosis complex (TSC) not requiring immediate surgery; advanced **renal cell carcinoma** (RCC) after sunitinib or sorafenib failure; prophylaxis of organ rejection in **renal transplant** patients; subependymal **giant cell astrocytoma** (SEGA) associated with TSC which requires intervention, but cannot be curatively resected; prophylaxis of organ rejection in **liver transplantation** (in combination with corticosteroids and reduced doses of tacrolimus)

Off-Label Uses: carcinoid tumors (progressive, advanced); Waldenström macroglobulinemia (relapsed or refractory)

Dosing: Dosing ranges from 2.5-10 mg per day but varies according to the disease being treated. See product literature

How Supplied: 2.5 mg, 5 mg, 7.5 mg, 10 mg oral tablets

Precautions*: angioedema; bone marrow suppression; graft thrombosis; infection (viral, bacterial protozoal, viral); skin cancer and lymphoma; hyperglycemia; hyperlipidemia; mucositis/stomatitis; nephrotoxicity; pulmonary toxicity; delayed wound healing

Drug Interactions: ACE inhibitors (increased ACEI toxicity); CYP3A4 Inducers (decreased serum concentration of everolimus); CYP3A Inhibitors, grapefruit juice (increased serum concentration of everolimus)

***NOTE:** See product literature for details

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HISTORY

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